

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lloyd WOLFINBARGER, et al.  
Serial No.: 09/528,371                      Group Art Unit: 1651  
Filed: MARCH 17, 2000              Examiner: Jon P. Weber, Ph.D.  
Title: A PROCESS FOR DECELLARIZING SOFT-TISSUE  
ENGINEERED MEDICAL IMPLANTS, AND DECELLULARIZED  
SOFT-TISSUE MEDICAL IMPLANTS PRODUCED

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §§ 1.97 and 1.98**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

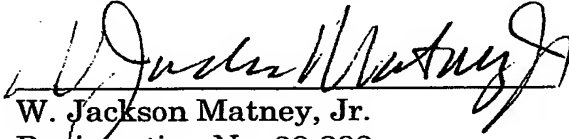
In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and/or listed herein and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

The present Information Disclosure Statement is being filed without a Certification under 37 CFR §1.97(e) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action or Notice of Allowance (whichever is earlier), and therefore a check for the fee of \$180.00 under 37 CFR §1.17(p) is attached. Please

charge any necessary fee or credit any overpayment in connection with this Information Disclosure Statement to Deposit Account No. 05-1323.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



W. Jackson Matney, Jr.  
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FORM PTO-1449 U.S. Department of Commerce Patent & Trademark Office  <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	Attorney Docket No. 10067.52083US	Serial No. 09/528,371
	Applicant: Lloyd WOLFINBARBER, et al.	
	Filing Date March 17, 2000	Group

U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)
	AA	2001/0049138	12/2001	Dennis, et al.			
	AB	6416995	07/2002	Wolfinbarger			
	AC	6293970	09/2001	Wolfinbarger, Jr.			
	AD	6024735	02/2000	Wolfinbarger, Jr.			
	AE	5997896	12/1999	Carr, Jr., et al.			
	AF	5993844	11/1999	Abraham, et al.			
	AG	5976104	11/1999	Wolfinbarger, Jr.			
	AH	5899936	05/1999	Goldstein			
	AI	5863531	01/1999	Naughton, et al.			
	AJ	5855620	01/1999	Bishopric, et al.			
	AK	5885617	01/1999	Orton			
	AL	5843182	12/1998	Goldstein			
	AM	5843181	12/1998	Jaffe, et al.			
	AN	5820581	10/1998	Wolfinbarger, Jr.			
	AO	5632778	05/1997	Goldstein			
	AP	5613982	03/1997	Goldstein			
	AQ	5558875	09/1996	Wang			
	AR	5556379	09/1996	Wolfinbarger			
	AS	5432712	07/1995	Chan			
	AT	5336616	08/1994	Livesey, et al.			
	AU	4801299	01/1989	Brendel, et al.			
	AV	4776853	10/1988	Klemet, et al.			
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			
<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.							

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		Filing Date March 17, 2000	Group

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)						
AW	Robert MADDEN, et al., "Decellularized Cadaver Vein Allografts Used for Hemodialysis Access Do Not Cause Allosensitization or Preclude Kidney Transplantation" Journal of Kidney Diseases, Vol. 40, No. 6, December 2002, pages 1240-1243					
AX	P.M. DOHMEN, et al., "In Vitro hydrodynamics of a decellularized pulmonary porcine valve, compared with a glutaraldehyde and polyurethane heart valve" Journal of Artificial Organs, Vol. 25, No. 11, 2002, pages 1089-1094					
AY	B. S. CONKLIN, et al., "Development and evaluation of a novel decellularized vascular xenograft" Medical Engineering and Physics, vol. 24, 2002, pages 173-183					
AZ	J. CLARK, et al., "Decellularized Dermal Grafting in Cleft Palate Repair" Facial Plastic Surg., Vol. 5, 2003, pages 40-44					
BA	Ronald C. ELKINS, et al., "Decellularized human Valve Allografts" Society of Thoracic Surgeons, 2001, pages S428-S432					
BB	Steven GOLDSTEIN, et al., "Transpecies Heart Valve Transplant: Advanced Studies of a Bioengineered Xeno-Autograft" Society of Thoracic Surgeons, 2000, pages 1963-1969					
BC	Pascal M. DOHMEN, et al., "Ross Operation with a Tissue-Engineered Heart Valve" Society of Thoracic Surgeons, 2002, pages 1438-1442					
BD	David W. COURTMAN, et al., "Biomechanical and ultrastructural comparison of cryopreservation and a novel cellular extraction of porcine aortic valve leaflets" Journal of Biomedical Materials Research, Vol. 29, 1995, pages 1507-1516					
BE	Gregory WILSON, et al., "Acellular Matrix Allograft Small Caliber Vascular Prostheses" Trans. Am. Soc. Artif. Intern. Organs, 1990, Vol. XXXVI, pages M340-M343					
BF	David W. COURTMAN, et al., "The Acellular Matrix Vascular Prosthesis: Investigation of its Potential as a Xenograft for Clinical Application" Biomaterial Tissue Interfaces, Vol. 10, 1992, pages 241-246					
BG	David W. COURTMAN, et al., "Development of a pericardial acellular matrix biomaterial: Biochemical and mechanical effects of cell extraction" Journal of Biomedical Materials Research, Vol. 28, 1994, pages 655-666					
BH	Gregory J. WILSON, et al., "Acellular Matrix: A Biomaterials Approach for Coronary Artery Bypass and Heart Valve Replacement" Society of Thoracic Surgeons, 1995, pages S353-S358					
BI	Sotiris A. KORROSSIS, et al., "Tissue Engineering of Cardiac Valve Prostheses II: Biomechanical Characterization of Decellularized Porcine Aortic Heart Valves" Heart Valve Disease, Vol. 11, No. 4, July 2002, pages 463-471					
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SOFT-TISSUE MEDICAL IMPLANTS PRODUCED

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

This supplements the Information Disclosure Statement submitted in the above-identified application on March 26, 2003.

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and/or listed herein and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

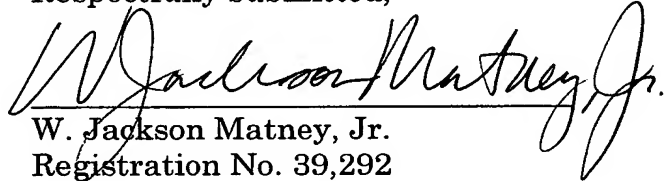
Applicant hereby notifies the Examiner of U.S. Patent Application No. 09/660,422, to Wolfinbarger et al., assigned to Examiner Jean C. Witz.

The present Information Disclosure Statement is being filed without a Certification under 37 CFR §1.97(e) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action or Notice of Allowance (whichever is earlier), and

therefore a check for the fee of \$180.00 under 37 CFR §1.17(p) is attached. Please charge any necessary fee or credit any overpayment in connection with this Information Disclosure Statement to Deposit Account No. 05-1323.

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U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)
	AA	6312474	11/2001	Francis, et al.			
	AB	6371992	04/2002	Tanagho, et al.			
	AC	6376244	04/2002	Atala			
	AD	6428802	08/2002	Atala			
	AE	6432710	08/2002	Boss, Jr., et al.			
	AF	6448076	09/2002	Dennis, et al.			
	AG	6479064	11/12202	Atala			
	AH	5843180	12/1998	Jaffe, et al.			
	AI	5916266	06/1999	Yui, et al.			
	AJ						

FOREIGN PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Sub-Class	TRANSLATION	
							Yes	No
	AK							
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)									
	AQ	H.-H. SIEVERS, et al., "Decellularized pulmonary homograft (SynerGraft) for reconstruction of the right ventricular outflow tract: first clinical experience" Z. Kardiol, Vol. 92, No. 53, 2003							
	AR								
	AS								

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